

CLAIMS

1. A monoclonal antibody suitable for monitoring the activity of systems involving protein C inhibitor, said 5 monoclonal antibody having specific affinity for both

- i) a complex between a serine proteinase and an inhibitor thereof, and
- ii) a cleaved and uncomplexed form of said inhibitor,

10 while having substantially no specific affinity for said inhibitor in its uncleaved and uncomplexed form; or a derivative thereof having the same biological activity.

15 2. A monoclonal antibody according to claim 1, wherein said monoclonal antibody is obtainable by immunisation of an animal with a mixture of

- i) a complex between a serine proteinase and an inhibitor thereof, and
- ii) a cleaved and uncomplexed form of said inhibitor,

20 followed by screening for and isolation of said monoclonal antibody.

25 3. A monoclonal antibody according to claim 2, wherein said animal is a mouse, preferably a Balb/c mouse.

30 4. A monoclonal antibody according to any one of the preceding claims, wherein said serine proteinase is selected from the group consisting of activated protein C (APC), thrombin, coagulation factor X_a, trypsin, chymotrypsin, urokinase plasminogen activator (uPA), tissue type plasminogen activator (tPA), plasma kallikrein, factor XI_a, HGK1 and prostatic specific antigen (PSA).

35 5. A monoclonal antibody according to any one of the preceding claims, wherein said inhibitor is protein C inhibitor (PCI) or α_1 -antitrypsin.

Sub A

Sub A3
~~6. A method for preparation of a monoclonal antibody as defined in any one of claims 1-5, wherein an animal is immunised with a mixture of~~

5 ~~i) a complex between a serine proteinase and an inhibitor thereof, and~~

~~ii) a cleaved form of said inhibitor,~~

~~followed by screening for and isolation of said monoclonal antibody.~~

10 ~~7. A method for preparation of a monoclonal antibody according to claim 6, wherein said animal is a mouse, preferably a Balb/c mouse.~~

15 ~~8. A method for monitoring the activity of systems involving protein C inhibitor, wherein a monoclonal antibody as defined in any one of claims 1-5 is used in an immunoassay.~~

~~9. A method according to claim 8, wherein said immunoassay comprises a sandwich-type immunoassay.~~

20 ~~10. A method according to claim 9, wherein said sandwich-type immunoassay is a technique comprising a tracer agent and said monoclonal antibody bound to a surface.~~

25 ~~11. A method according to claim 10, wherein said tracer agent comprises an antibody having specific affinity for said serine proteinase or an epitope shared by said serine proteinase and said inhibitor.~~

~~12. A method according to claim 11, wherein said tracer agent is conjugated to a suitable enzyme and/or labelled with a tracing substance.~~

30 ~~13. A method according to claim 12, wherein said enzyme is an alkaline phosphatase, horse radish peroxidase or a β -galactosidase.~~

~~14. A method according to claim 13, wherein said tracing substance is ^{125}I , ^{131}I , Eu^{3+} or Sm^{3+} or a similar lanthanide.~~

35 ~~15. A method for diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders~~

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involving lupus anticoagulants, wherein a monoclonal antibody according to any one of claims 1-5 is utilised.

16. A method for diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders involving lupus anticoagulants, wherein a method according to any one of claims 8-14 is utilised.

17. Use of a monoclonal antibody according to any one of claims 1-5 for in vitro diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders involving lupus anticoagulants.

18. Use of a method according to any one of claims 8-14 for in vitro diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders involving lupus anticoagulants.

19. A kit for qualitative or quantitative determination of the activity of systems involving protein C inhibitor comprising a monoclonal antibody according to any one of claims 1-5.

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